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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,406

11/18/2005

Tomasz Troczynski

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EXAMINER

ELLIS, SUEZU Y

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,406	Applicant(s) TROCZYNSKI ET AL.	
	Examiner Suezu Ellis	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11-13 and 37-43 is/are pending in the application.
- 4a) Of the above claim(s) 38-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11-13 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I and species (i) in the reply filed on May 6, 2008 is acknowledged.

Claims 38-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 6, 2008.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 7, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 8, 9 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al. (US 6,113,993).

With respect to claim 1, Gao et al. discloses an implant comprising a substrate and calcium phosphate coating on the substrate, wherein the coating has a thickness of less than 1 μm . Applicant's claim language does not provide any structural limitations limiting the system to a stent - therefore, the limitation in the preamble of the system as recited is directed towards an intended use of the system, and hence, will be given little patentable weight.

With respect to claims 2 and 13, Gao et al. discloses the calcium phosphate coating comprises hydroxyapatite and/or tricalcium phosphate (abstract).

With respect to claim 8, Gao et al. discloses the substrate is stainless steel (col. 3, lines 5-8).

With respect to claim 9, Gao et al. discloses the calcium phosphate coating is porous and the pores retain and elute a drug (col. 1, lines 37-39; col. 2, lines 33-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al.

With respect to claims 3 and 4, Gao et al. addresses all the limitations of claim 1, and further discloses the thickness of the calcium phosphate coating is less than 1 μm , however fails to expressly disclose the exact thickness range. It would have been obvious to one of ordinary skill in the art to modify the thickness through routine or manipulative experimentation in order to obtain the best possible results. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 7, Gao et al. addresses all the limitations of claim 1, however fails to expressly disclose the coating covers about 20% to about 99% of the surface of the substrate. However, Gao et al. does disclose coating the substrate, therefore it is reasonable interpretation that coating covers about the entire substrate. Therefore, examiner considers the coating of Gao et al. to cover about 99% of the surface of the substrate.

Claims 5 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. in view of Zhang et al. (US 7,157,096)

With respect to claims 5 and 37, Gao et al. addresses all the limitations of claim 1, however fails to expressly disclose the tensile bond strength value between the substrate and the calcium phosphate. Zhang et al. teaches implants having multi-layers comprising hydroxyapatite having a bond strength greater than or equal to 60MPa (col. 10, lines 14-24; col.18, lines 62-65). It would have been obvious to one of ordinary skill

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in the art to modify the bond strength in order to provide a layer sufficiently bonds to the substrate.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. in view of Zhang et al. and further in view of Falotico et al. (US 2001/0029351).

With respect to claim 11, Gao et al. addresses all the limitations of claims 1 and 9, however fails to expressly disclose the substrate has two calcium phosphate coatings where a drug is contained in both coatings. Zhang et al. teaches an implant having two calcium phosphate coatings and a drug contained in the second coating (col. 4, lines 32-36; col. 6, lines 33-41). It would have been obvious to one of ordinary skill in the art to include two calcium phosphate coatings in order to provide an implant with an increased biocompatibility (col. 10, lines 58-60). However, Zhang et al. fails to expressly disclose a drug is contained in the first coating. Falotico et al. discloses an implant (stent) having two coatings where a drug is present in each coating (Figs. 3-5). It would have been obvious to one of ordinary skill in the art to utilize two calcium phosphate coatings with a drug in each coating in order to create to provide the most efficacious treatment for post-angioplasty restenosis [0032].

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. and further in view of Falotico et al.

With respect to claim 12, Gao et al. addresses all the limitations of claims 1 and 9, however fails to expressly disclose the drug inhibits restenosis. Pacetti discloses the

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stent is used to prevent restenosis and comprises a therapeutic drug (col. 6, lines 45-52; col. 10, lines 13-14). However, the modified Pacetti fails to expressly disclose the drug inhibits restenosis. Nevertheless, it is well known in the art for implants to have a coating comprising a drug for inhibiting restenosis, as taught by Falotico [0018], [0032]. It would have been obvious to one of ordinary skill in the art to include a drug for inhibiting restenosis in order to improve the treatment for restenosis [0032].

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. and further in view of Kotte et al. (US 2003/0031983).

With respect to claim 37, Gao et al. addresses all the limitations of claim 1, however fails to expressly disclose the calcium phosphate coating is an electrochemically deposited coating. Kotte et al. teaches it is well known in the art to apply calcium phosphate coatings via electrochemical deposition. It would have been obvious to one of ordinary skill in the art to apply the calcium phosphate layer via electrochemical deposition in order to produce uniform and thin calcium phosphate coatings, as desired [0003].

Claims 1, 3, 4, 7-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (US 6,663,664) in view of Gao et al.

With respect to claims 1, 8, 9 and 13, Pacetti discloses a stent for preventing restenosis comprising a substrate (stainless steel stent) and a coating of tricalcium phosphate (col. 9, lines 50-51; col. 10, line 9, 21-22). Pacetti fails to expressly disclose

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the thickness of the coating. Gao et al. teaches coating an implant with tricalcium phosphate and the thickness of the coating being less than 1 μm (col. 3, lines 58-61). It would have been obvious to one of ordinary skill in the art to modify the thickness of the coating in order to provide a coating that will not become separated from the implant due to large residual stress.

With respect to claims 3 and 4, the modified Pacetti addresses all the limitations of claim 1, however fails to expressly disclose the exact thickness range. It would have been obvious to one of ordinary skill in the art to modify the thickness through routine or manipulative experimentation in order to obtain the best possible results. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 7, the modified Pacetti discloses the coating covers about the entire substrate, thus is considered to cover about 99% of the surface of the substrate (col. 10, lines 58-60).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Gao et al. and further in view of Zhang et al. and further in view of Falotico et al.

With respect to claim 11, the modified Pacetti addresses all the limitations of claims 1 and 9, however fails to expressly disclose the substrate has two calcium phosphate coatings where a drug is contained in both coatings. Zhang et al. teaches an

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implant having two calcium phosphate coatings and a drug contained in the second coating (col. 4, lines 32-36; col. 6, lines 33-41). It would have been obvious to one of ordinary skill in the art to include two calcium phosphate coatings in order to provide an implant with an increased biocompatibility (col. 10, lines 58-60). However, Zhang et al. fails to expressly disclose a drug is contained in the first coating. Falotico et al. discloses an implant (stent) having two coatings where a drug is present in each coating (Figs. 3-5). It would have been obvious to one of ordinary skill in the art to utilize two calcium phosphate coatings with a drug in each coating in order to create to provide the most efficacious treatment for post-angioplasty restenosis [0032].

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Gao et al. and further in view of Falotico et al.

With respect to claim 12, the modified Pacetti addresses all the limitations of claims 1 and 9, however fails to expressly disclose the drug inhibits restenosis. Pacetti discloses the stent is used to prevent restenosis and comprises a therapeutic drug (col. 6, lines 45-52; col. 10, lines 13-14). However, the modified Pacetti fails to expressly disclose the drug inhibits restenosis. Nevertheless, it is well known in the art for stents to have a coating comprising a drug for inhibiting restenosis, as taught by Falotico [0018], [0032]. It would have been obvious to one of ordinary skill in the art to include a drug for inhibiting restenosis in order to improve the treatment for restenosis [0032].

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Gao et al. and further in view of Kotte et al.

With respect to claim 37, the modified Pacetti addresses all the limitations of claim 1, however fails to expressly disclose the calcium phosphate coating is an electrochemically deposited coating. Kotte et al. teaches it is well known in the art to apply calcium phosphate coatings via electrochemical deposition. It would have been obvious to one of ordinary skill in the art to apply the calcium phosphate layer via electrochemical deposition in order to produce uniform and thin calcium phosphate coatings, as desired [0003].

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615